

Serial No. 10/784,418
Amendment Dated 07/08/2005
Reply to Office Action of 03/18/2005

REMARKS/ARGUMENTS

Objections

Drawings

The specification has been amended so that it no longer contains Figures or references to Figures.

Claim Objections

Claim 1 was objected to because of several informalities. The claim has been amended as suggested by the Examiner and now is in proper form.

Priority

The priority paragraph has been amended to more precisely indicate the status of the parent application.

Claim rejections under 35 USC § 112

Claims 1-3 are rejected under U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time of the application was filed, had possession of the claimed invention. In the rejection it is stated that, "There is no written description of the elite maize genotypes used as the different maize plant to be crossed with Hi-II plants in terms of their genetic, morphological, and/or physiological background."

Applicants traverse. The Applicants respectfully point out that on page 7, starting on line 13, and continuing through line 30 on page 11, there is a list of examples of potential maize lines that may be used in the invention. Specifically of note are PHN46, PHP02, PH05F, PH09B, and PHAA0. The instant application

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reports data obtained from the use of these maize lines in the invention (Table 1, page 38). The specification also identifies the patent for each of these maize lines. The corresponding patents use morphology and physiology to describe the maize lines. The patents also disclose the genetics through disclosure of an ATCC deposit. Indicated in the table below are some of the inbreds and examples of their differences indicated through their respective patents. Through use of the referenced patents one can determine other physiological and morphological differences which are evidence of genetic diversity. For example PHP02 is susceptible to Head Smut and PHAA0 is highly resistant to Head Smut.

variety	ref. pg. in spec.	Patent #	Area of adaptation and/or relative maturity (RM)	Silk color	Anther color
PHN46	pg. 9	5,567,861	Central corn belt 110-122 RM	pink	yellow
PHP02	pg. 11	5,082,992	Northern corn belt 94-114 RM	salmon	yellow
PH05F	pg. 9	5,608,139	Central corn belt 109 RM	yellow	pink
PHAA0	pg. 9	5,602,317	Early maturity	yellow	yellow
PH09B	pg. 9	5,859,354	Central corn belt and western region of U.S.	yellow	pink
PHJ90	pg. 9	5,245,125	106-118 RM	pink	pink
PHT4	pg. 9	5,569,822	North Central U.S.	green	purple

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Claim rejections under 35 USC § 112

Claims 1-3 are rejected under U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the rejection it is stated that, "There is no guidance provided regarding the genetic, morphological, and/or physiological background, or of their degree of relatedness to each other...Applicant has not taught how to make and use the myriad of different hybrids that may be produced from the result of manifested genetic variation combined with selection methods, environments and the action of the breeder without undue trial and error."

Applicants traverse. When determining the quantity of experimentation necessary, the focus is not on the amount of experimentation necessary to practice the entire genus, but the amount of experimentation required to practice any particular member. This concept is the central holding of *In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) where the claims read on the use of any IgM antibody that possessed a particular binding affinity.

The Examiner maintains that the undue experimentation lies in the process of identifying different hybrids that may be produced from the result of manifested genetic variation combined with selection methods, environments and the action of the breeder.

However, the *Wands* court recognized that it would require an infinite amount of experimentation to obtain every single possible IgM antibody that could be generated with the specified affinity. Accordingly, the court focused on the amount of experimentation necessary to practice any particular IgM antibody with the recited binding affinity and not the amount of experimentation required to practice the entire genus.

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This focus is further supported by the multitude of chemical patents that have issued with generic claims reading on tens to hundreds of thousands of individual members.

The question then becomes how much experimentation is required to create the present claimed invention. Applicants submit that no more than routine experimentation is required. This may be accomplished by the methods disclosed in the present application and within the technical, scientific, skill in the art.

Applicants assert the present invention is disclosed in a way that one skilled in the art will be able to practice it without an undue amount of experimentation. Applicants submit that they have fully described the present invention as claimed by teaching both how to make and how to use the invention in a manner commensurate in scope with the claims.

The USPTO carries the initial burden to establish a reasonable basis for questioning the enablement provided for the claimed invention. As stated in *In re Wright*, 99, F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); MPEP § 2164.04, the enablement requirement is satisfied if the specification describes any method for making and using the claimed invention that bears a "reasonable correlation" to the entire scope of the claims. Applicants submit that this has been accomplished in the present application.

Embryos from hybrids obtained with increased transformation efficiency could easily be tested for activity using the methods outlined in the present application. "That one skilled in the art must perform some preliminary tests or experiments before he can make or use the invention does not invalidate the patent" on the basis of section 112. *Atlas Powder Co. v. E. I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984).

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Claim rejections under 35 USC § 102

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhao et al (US Patent 5,981,840). The Examiner suggests that the rejection under 102(e) might be overcome by the a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another".

Applicants submit a 37 CFR 1.132 declaration. The declaration is attached. Zuo-Yu Zhao is a co-inventor of both the instant application and patent 5,981,840, which were co-pending.

Claim rejections under 35 USC § 103

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being anticipated by Zhao et al (US Patent 5,981,840).

Applicants point out that Claim 1 has been amended and Claims 2 and 3 depend from Claim 1. Claim 1 now reads in part, "A method of developing a maize embryo that has increased transformation efficiency comprising crossing a Hi-II maize plant to a different maize plant other than a second Hi-II maize plant, to obtain a maize embryo". If a Hi-II is crossed with a sister plant it would not be crossed with a different maize plant other than a second Hi-II maize plant.

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CONCLUDING REMARKS

Applicant has amended the specification and amended Claim 1. No new matter has been added by amendment. Reexamination and reconsideration of the claims as amended are respectfully requested. In view of the above comments and amendments, withdrawal of the outstanding rejection and allowance of the Claims 1-3 is respectfully requested.

Respectfully submitted.



Kim M. Hagemann
Agent for Applicant(s)
Registration No. 52,982

PIONEER HI-BRED INTERNATIONAL, INC.
Corporate Intellectual Property
7100 N.W. 62nd Avenue
P.O. Box 1000
Johnston, Iowa 50131-1000
Phone: (515) 248-4878
Facsimile: (515) 334-6883